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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,344	09/10/2004	Lauretta Maggi	28069-602 NATL	3801

7590 12/10/2008
Daniel Coughlin
Mintz Levin Cohn Ferris Glovsky & Popeo
666 Third Avenue
New York, NY 10017

EXAMINER

AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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12/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,344	Applicant(s) MAGGI ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants': (1) amendment and (2) RCE, both filed on 17 September 2008.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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Specifically, claim 1 recites a tablet, "...completely covered by a film..."

However, this limitation contradicts the description of the tablet in the specification.

According to the instant specification,

...one can obtain filmed tablets, coated all over the surfaces with the exception of one or two portions of the surfaces exactly defined and measurable, as schematically reported in Figures 2 and 3...That means that all the surfaces of the tablet are impermeable to aqueous liquids with the exclusion of the only surface devoid of coating. In fact, the incision in the coating film allows the penetration into the nucleus of the dissolving liquid. (See page 13, lines 21-27, emphasis added).

Thus, according to the description, the disclosed tablet, by definition, is not completely covered by a film. Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2, 4, 5, and 8-25 are rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,487,901 ("Conte").

Conte discloses a pharmaceutical tablet composed of an upper layer containing active ingredient, formulated for immediate release, an intermediate layer that does not

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contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being almost completely coated with an insoluble polymeric coating (col. 2, lines 30-45). The tablet is completely coated with an impermeable polymeric film (col. 2, lines 52-53). The upper layer also comprises polymeric excipients (col. 4, lines 1-9). The amount of the excipient with respect to the total weight of the tablet is 1-90% by wt (col. 4, lines 10-13). The upper layer is 0.5-5 mm thick (col. 4, line 39). The intermediate layer is made of gelable or erodible polymers (col. 4, lines 40-53). The amount of polymeric substance in respect of the total weight of the tablet is 5-90% (col. 4, lines 55). The intermediate layer is 0.1-4.5 mm thick (col. 5, lines 31). The third layer has the same composition as the upper layer (col. 5, lines 32-36). The lower layer is 0.5-5 mm thick (col. 5, line 37). The tablet is coated with an impermeable polymeric material that is insoluble or exhibits delayed solubility, or a solubility that is pH dependent (col. 5, lines 40-46). The polymeric coating in respect of the finished tablet is 0.2-20% by wt (col. 5, lines 54-55). The upper layer is partially exposed to the environmental fluid because a raised portion was removed after final coating with impermeable polymeric coating (col. 2, lines 54-55). The reference discloses that the removal of the raised portion may be carried out by techniques already available on the market (col. 5, lines 61-64). This teaching does not rule out using laser to remove the raised portion. In any case, as was stated above in the previous rejection, claim 1 is a product by process claim. The process by which a product is made will only hold patentable weight if the process imparts functional or

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structural limitations to the product that would distinguish it from the product of the prior art. In this case the prior art clearly anticipates the instant claimed product, and therefore the process limitation of using a laser to incise the impermeable polymeric membrane in the product claims does not impart patentable weight. The burden is upon applicant to show that instant product is patentably distinct from Ayer's product.

*

2. Claims 1, 2, 4, 5, 8-25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,650,169 ("Conte").

Conte '169 is a divisional of Conte '901. The disclosures are identical and the disclosure of '169 discloses all of the limitations discussed in the previous rejection. See above.

*

3. Claims 1, 3, 6-27 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,599,284 ("Faour").

Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), an intermediate layer forming a semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4). The dosage form also comprises a passageway (5) formed by laser incision (col. 13, lines 48-55), which is incised in correspondence with both the first and third layer (Figure 4). The reference also teaches the addition of osmopolymers (col. 16, lines 1--45), and disintegrating agents (col. 18, lines 25-38)° The reference further discloses that the outer layer or external coating layer may contain the same or different

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active ingredients as the inner layer (col. 13, lines 5-7). Example 1 discloses the composition of the inner core, which comprises more than 49% by wt polymeric material (col. 24, lines 15-25). Example 1 also discloses the use 5% by wt of polyethylene glycol (col. 24, lines 25-30). Faour incorporated by reference Theeuwes et al. US 4088864, which discloses the laser source as CO₂ and the output of 20W. Therefore the process claims are also anticipated by this reference.

* * * * *

Response to Arguments

Applicants' arguments filed on 17 September 2008 have been fully considered but they are not persuasive.

1. Applicants argue, "...it is the incision(s) on the claimed tablet, which comprise an impermeable coating that fully covers the active ingredients and remains intact until the moment of use so that it protects the active ingredients contained therein, which alters the release profile, with a pre-determinable and programmable release rate, which differs by at least 10% from the release profiles of Conte, i.e. a structural and functional limitation." See remarks, page 6.

As explained in the 35 USC 112 rejection, above, the coating of the instantly claimed tablet does not "fully cover" the active ingredients of the tablet. Rather, the incisions create gaps in the coating which expose the core to the outside environment before the tablet is introduced to an aqueous environment (see page 13, lines 21-27).

Furthermore, as explained in the previous Office action, the data disclosed in Exhibit A and Exhibit B do not control for formulation excipients such as binders, fillers,

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disintegrants, etc. Thus, it is not possible to conclude that the release profiles disclosed in the graphs of Exhibit A and Exhibit B are a sole function of coating structure. Furthermore, it is not clear what the difference is in the formulations EG 1-EG 8 of Exhibit A and Examples 1-6B of Exhibit B. Also not disclosed are the size, shape, and number of incisions in the tablets of Exhibit B. Without more information, examiner respectfully submits that it is not possible to determine the cause of any difference of release profiles between Exhibit A and Exhibit B.

As such, examiner respectfully submits that the instantly disclosed tablet, as claimed in instant claim 1 is neither structurally nor functionally distinguished from the prior art.

2. Applicants argue that the instant application is distinguished from the prior art in that the newly added limitation to claim 1 recites that the film coating "...remains intact until the moment of use so that it protects the active ingredients contained therein..."

See remarks, page 6

Examiner respectfully submits that the coating of the prior art also remains intact until the moment of use. As explained in the 35 USC 112 rejection, above, the coating of the instantly claimed tablet cannot (by definition) be continuous, since the incision creates a gap in the coating similar to the gap in the coating of the prior art.

3. Applicants argue that Faour does not disclose a coating that remains intact until the moment of use. See remarks, page 7.

Examiner respectfully submits that the coating of Faour indeed remains intact until the moment of use. As explained in the 35 USC 112 rejection, above, the coating

of the instantly claimed tablet cannot (by definition) be continuous, since the incision creates a gap in the coating. This gap is similar to the passageway of Faour.

★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

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/Humera N. Sheikh/
Primary Examiner, Art Unit 1615